

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

THE UNITED STATES OF AMERICA *et al.*
ex rel. JULIE LONG,

Plaintiffs,

Civil Action No. 16-CV-12182-FDS

V.

JANSSEN BIOTECH, INC.,

Defendant.

**PLAINTIFF-RELATOR’S BRIEF CONCERNING
HER PROPOSED PRETRIAL SCHEDULE**

Plaintiff-relator Julie Long submits this brief to present her proposed pretrial schedule, including a schedule for the phase one summary judgment proceeding, and to demonstrate that Janssen’s proposed schedule wholly disregards the phased discovery plan that has been governing the discovery process in this case – a plan that the Court entered at Janssen’s request.

I. An Overview of the First Phase of the Court's Phased Discovery Plan

The Court's Creation of the Phased Discovery Plan

Relator alleges that, from the early 2000s until at least 2020, Janssen engaged in a nationwide strategy and scheme to induce targeted physician practices to prescribe its drugs Remicade and Simponi ARIA—two drugs administered via infusion—to patients, including Medicare beneficiaries, by providing the physicians free consultative services and support to assist and advise them on opening and enhancing the operation of an in-office infusion suite (IOI) within their practices. The free consultative services and support and the sessions or programs through which most of the services and support were provided are collectively referred to herein as “IOI Support.” Relator alleges that by providing the IOI Support to customers to

induce them to prescribe and infuse Remicade and Simponi ARIA to Medicare patients Janssen violated the Anti-Kickback Statute (AKS), 42 U.S.C. § 1320a-7b. Additionally, because Medicare does not cover medical treatments that result from a kickback, Relator alleges that the claims for reimbursement for Remicade and Simponi ARIA and related infusion procedures that the recipients of the IOI Support subsequently submitted to Medicare (and that Medicare paid) constituted false claims that Janssen caused to be presented in violation of the False Claims Act, 31 U.S.C. § 3729.

In denying Janssen's motion to dismiss, the Court concluded that Relator's complaint sufficiently alleges a nationwide kickback scheme that caused false claims to be submitted to Medicare. *See* ECF 75 at 33. However, the Court indicated that before it allows Relator to obtain nationwide discovery concerning the IOI Support that she alleges Janssen provided to targeted customers it might "probe the validity of [Relator's] kickback allegations." Oct. 21, 2020 Mem. & Order (ECF 75) at 33 n.12. Janssen thereafter filed a motion requesting the Court to impose a phased discovery approach. *See* ECF 86. In accordance with its motion to dismiss ruling and Janssen's motion, the Court ordered that discovery will be conducted in phases. *See* Dec. 14, 2020 Conf. Tr. (ECF 90) at 4-5, 10-11.

As the Court explained during the initial scheduling conference and later clarified in subsequent conferences and decisions, this first phase of discovery is focused on the IOI Support that Relator alleges Janssen provided—through her and outside consultants—while Relator was employed at Janssen (2003 to February 2016) to a sample group of IOI customers from her former territory. *See id.* at 10-11; Sept. 9, 2022 Order (ECF 320) at 2-3. In accordance with the Court's directive, the sample group consists of nine customers that Relator specifically identified in her complaint plus two to three additional customers selected by Relator. *See id.* at 10-11.

Under this discovery plan, in addition to the IOI Support provided to the sample accounts, the Court has permitted Relator to obtain discovery going up her chain of command and of non-field level employees who had significant involvement in the development, review, approval, monitoring, and/or delivery of the national strategy and policies pursuant to which Relator provided or observed others provide the IOI Support to customers in the phase one sample group. The Court ordered that, except for documents concerning Relator, Relator's specific allegations or claims, Janssen's termination or phasing-out of the IOI Support programs that Relator provided or personally observed, or the legality or illegality of providing the IOI Support, the production of documents during the first phase is limited to documents created through February 2016. *See* Sept. 9, 2022 Order (ECF 320) at 3. The Court directed that after this initial phase of discovery is complete it "will provide defendants an opportunity to test the allegations of the complaint by summary judgment." *See id.* at 2.

***Relator Has Been Conducting Discovery in Accordance
with the Limitations Imposed by the Court's Plan***

Relator has been conducting discovery in compliance with the Court's plan, as well as the Court's numerous orders deciding what discovery is allowed during this phase, and will complete phase one discovery in accordance with the Court's schedule.

Importantly, under the Court's plan, Relator is not permitted to obtain discovery concerning the following factual areas until after the Court has tested her allegations and allows discovery to proceed to the next phase:

- (1) Janssen's provision of the IOI Support to customers after February 2016;
- (2) Janssen's provision of the IOI Support to the other customers in Relator's former territory (beyond those customers included in the phase one sample group);
- (3) Janssen's provision of the IOI Support to customers in other territories; and

- (4) Certain categories of relevant documents and information that the Court has ruled Janssen does not need to provide during this first phase.

The Court Should Postpone Non-Party Discovery Concerning the Issue of Causation Until the Governing Standard in this Circuit Is Decided

Because the standard for proving that an alleged false claim for Medicare reimbursement “resulted from” an AKS violation is an unsettled question that is pending before the First Circuit, the Court appropriately instructed that a summary judgment motion directed at the issue of causation cannot be decided until after the governing standard has been decided. *See* Tr. of Mar. 13, 2024 Conf. (ECF 439) at 10-11.

Similarly, because the standard that will govern the causation issue is currently unknowable, Relator should not have to conduct discovery of non-parties, such as recipients of the alleged kickbacks, or engage experts to opine on causation until after the governing standard has been decided. Such discovery and expert reports would entail the expenditure of significant resources and expense that, depending on the standard adopted, could be unnecessary and wasteful. If the governing standard is decided before Janssen’s phase one motion for summary judgment is due, then any necessary non-party discovery concerning causation should be completed before Janssen is required to file its motion. But if the standard for causation remains undecided when Janssen files its phase one motion for summary judgment, then any necessary non-party discovery concerning causation should be completed during phase two discovery.

II. Relator’s Proposal Concerning the Phase One Summary Judgment Process and a Pretrial Schedule

Relator submits that the phase one summary judgment proceeding should start with Janssen filing its phase one motion for summary judgment including the disclosure of reports or affidavits setting forth any expert opinions that Janssen seeks to present in support of such motion. The Court will determine whether it wants any expert testimony submitted in support of

the motion to be presented in the form of a report or an affidavit. If Janssen presents expert testimony in support of its motion, Relator should then have an opportunity to depose Janssen's expert(s). Irrespective of whether Janssen presents expert testimony in support of its motion, Relator should be afforded sufficient time to present reports or affidavits setting forth any expert opinions that she seeks to present in support of her opposition to arguments Janssen asserts in its motion. Thereafter, Janssen should have an opportunity to depose any expert(s) Relator uses. Once the phase one expert testimony process is complete, Relator will be in a position to prepare and submit her opposition to Janssen's phase one motion for summary judgment. A proposed schedule summarizing this process, which would allow a fair testing of Relator's allegations at the end of the first phase of discovery, is provided below.

Assuming the case proceeds beyond phase one to a second phase, the Court would decide on a reasonable amount of time for the parties to complete phase two of discovery, during which Relator should be permitted to obtain the four categories of discovery that she has been precluded from obtaining in phase one (*see* Part I above) along with any necessary non-party discovery concerning the causation issue. After phase two discovery is complete, Relator will designate her trial experts and disclose their reports, after which Janssen will designate its trial experts and disclose their reports. Expert discovery will also be completed. *Both parties* will then have an opportunity to file a motion for summary judgment. If the Court determines there are genuine issues of material fact that must be tried to a jury, the case will then proceed to trial.

Relator's proposal for the phase one summary judgment process and pretrial schedule is as follows:

	EVENT	PROPOSED DUE DATE
1	Completion of Phase One fact discovery	September 30, 2024
2	Defendant's Phase One Motion for Summary Judgment including the disclosure of reports or affidavits setting forth any expert opinions that Defendant seeks to present in support of its Phase One Motion for Summary Judgment	30 days from Event 1
3	Completion of depositions of experts whose opinions Defendant seeks to present in support of its Phase One Motion for Summary Judgment	30 days from Event 2
4	Disclosure of reports or affidavits setting forth any expert opinions that Relator seeks to present in support of her opposition to Defendant's Phase One Motion for Summary Judgment	30 days from Event 3
5	Completion of depositions of experts whose opinions Relator seeks to present in support of her opposition to Defendant's Phase One Motion for Summary Judgment	30 days from Event 4
6	Relator's opposition to Defendant's Phase One Motion for Summary Judgment	14 days from Event 5
7	Defendant's reply in further support of its Phase One Motion for Summary Judgment	14 days from Event 6
8	Relator's sur-reply in further opposition to Defendant's Phase One Motion for Summary Judgment	14 days from Event 7
9	<i>Decision on Defendant's Phase One Motion for Summary Judgment</i>	
10	Completion of Phase Two fact discovery	To be determined by the Court
11	Relator's trial experts must be designated, and the information contemplated by Fed. R. Civ. P. 26(a)(2) must be disclosed	30 days from Event 10
12	Defendant's trial experts must be designated, and the information contemplated by Fed. R. Civ. P. 26(a)(2) must be disclosed	30 days from Event 11
13	Relator's trial experts' rebuttal reports	20 days from Event 12
14	Completion of expert discovery	40 days from Event 13
15	Dispositive motions	30 days from Event 14
16	Oppositions to dispositive motions	40 days from Event 15
17	Reply brief in further support of dispositive motion	14 days from Event 16
18	Sur-Reply brief in further support of opposition to dispositive motion	14 days from Event 17
19	Initial pretrial conference	To be determined by the Court
20	Final pretrial conference / Trial	To be determined by the Court

III. Janssen's Proposal Disregards that this Case Is Being Litigated Under a Phased Discovery Plan – a Plan Janssen Requested

Under the proposed schedule that Janssen shared with Relator, after phase one discovery, the case would convert to a normal litigation and there would be no second phase of discovery before the case is tried.

Relator Should Not Be Required to Designate and Disclose Her Trial Experts at the End of the First Phase of Discovery

Janssen requests that the Court enter a schedule that would require Relator, after the end of phase one discovery, to designate the experts she may use at trial and disclose their expert reports in accordance with Federal Rule of Civil Procedure 26(a)(2). Thus, Janssen wants the Court to force Relator to select and disclose the experts she plans to use at trial before she is even provided full discovery of her allegations and Janssen's defenses and before the Court conducts its phase one test of Relator's allegations. Janssen's proposed schedule is entirely inconsistent with the purpose of the phased discovery approach and would be patently unfair and prejudicial to Relator, as it would require her to incur the substantial expense of having experts prepare reports that would be based upon only an assessment of a portion of the relevant evidence and would need to be disclosed before Relator even knows what arguments Janssen is asserting in its phase one summary judgment motion.

As explained in Part I above, the phased discovery approach, which Janssen requested, was instituted to allow Janssen to test Relator's allegations before discovery is expanded to cover (i) the remaining IOI customers that received the alleged kickbacks (beyond the sample accounts specifically referenced in Relator's complaint); (ii) the full period Janssen provided the alleged kickbacks (beyond the date Relator left Janssen); and (iii) other categories of relevant documents and information. Relator should not have to designate her trial experts and incur the expenses

related to expert reports until after the phase one summary judgment process and after she has been afforded an opportunity to obtain *full discovery* of her claims and Janssen's defenses.

Moreover, the phased approach and phased summary judgment process were instituted to allow Janssen an opportunity to raise and litigate any dispositive defects in Relator's claims to determine whether Relator should be permitted to obtain full discovery. This is not a normal summary judgment process where both parties have the ability to move for summary judgment after having had an opportunity to take full discovery of their claims; rather, this is a one-sided process to determine whether Relator is allowed to obtain full discovery of her claims. Requiring Relator to disclose all expert testimony she may use at trial at the end of phase one discovery and before the Court tests Relator's allegations to determine whether she can obtain full discovery of her claims would be entirely inconsistent with the phased approach and obviously prejudicial.

For these reasons, Relator should not be required to disclose any expert opinions beyond those she believes are necessary to respond to and defeat Janssen's phase one motion for summary judgment until after phase two of discovery has been completed.

A Second Phase of Discovery Is Required Before the Case Can Be Tried to a Jury

Under Janssen's proposed schedule, there would be no second phase of discovery before trial. Consequently, the case would be tried based on the limited evidence obtained during phase one – discovery concerning a small sample of accounts and covering only a portion of the relevant period. Janssen's proposed schedule and trial approach should not be approved because it is inconsistent with the Court's phased discovery plan and would also lead to substantial prejudice. Instead, the Court should adopt Relator's approach, which provides for the completion of phase one discovery in accordance with the Court's plan and allows for Relator to subsequently obtain full discovery before proceeding to a trial of her claims.

Dated: April 10, 2024

Respectfully submitted,

/s/ Theodore J. Leopold

Theodore J. Leopold (admitted pro hac vice)

Leslie M. Kroeger (admitted pro hac vice)

Diana L. Martin (admitted pro hac vice)

Poorad Razavi (admitted pro hac vice)

COHEN MILSTEIN SELLERS & TOLL PLLC

11780 U.S. Highway One, Suite N500

Palm Beach Gardens, FL 33408

(561) 515-1400

tleopold@cohenmilstein.com

lkroeger@cohenmilstein.com

dmartin@cohenmilstein.com

prazavi@cohenmilstein.com

Casey M. Preston (admitted pro hac vice)

Gary L. Azorsky (admitted pro hac vice)

Jeanne A. Markey (admitted pro hac vice)

Adnan Toric (admitted pro hac vice)

COHEN MILSTEIN SELLERS & TOLL PLLC

100-120 N. 18th Street, Suite 1820

Philadelphia, PA 19103

(267) 479-5700

cpreston@cohenmilstein.com

gazorsky@cohenmilstein.com

jmarkey@cohenmilstein.com

atoric@cohenmilstein.com

Jonathan Shapiro (BBO No. 454220)

SHAPIRO & TEITELBAUM LLP

55 Union Street, 4th Floor

Boston, MA 02108

(617) 742-5800

jshapiro@jsmtlegal.com

Counsel for Plaintiff-Relator Julie Long

Certificate of Service

I hereby certify on this 10th day of April, 2024, that this document filed through the CM/ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing.

/s/ Theodore J. Leopold

Theodore J. Leopold (admitted pro hac vice)